

ANDERSON EXHIBIT 26Q

unable to obtain discounts, but when large volume buying groups are formed, most are routinely locked out. Thus, like Medicaid, most pharmacists have been unable to obtain the best prices possible.

While we are concerned that best price may have adversely affected some of our members in the short term, it has the potential to reduce the negative effects of discriminatory pricing. This will benefit the public generally, and will lay the foundation for moving away from a product-driven payment system to a system which recognizes pharmacy services such as counselling and drug therapy management. The opportunity for patients to receive these services will continue to be inhibited as long as there are escalating prices and discriminatory pricing practices. Pharmacists and patients must support programs that will ensure more equitable prices and payment systems -- thus facilitating pharmacists' comprehensive role in patient care.

Some have argued that a flat percentage rebate is more appropriate. APhA believes a flat rebate would represent nothing more than a flat tax to do business with the government, which would force manufacturers to build this tax into their prices. The impetus behind the OBRA-90 Medicaid rebate law was to ensure patient access to needed drugs by enabling Medicaid to take advantage of discounted prices. Since the rebate provision took effect in 1991, we have witnessed unanticipated rebate levels to the states, and a return to rational, defensible pricing policies by the industry. Continuation of

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the best price methodology will ensure that the government indeed gets the best price.

In summary, the best price provisions have given Medicaid the chance to benefit from the leverage exerted by other pharmaceutical purchasers in realizing significant discounts. In addition, it has moderated overall drug price increases. The Medicaid best price methodology works, and should be maintained. Preliminary results have been very positive. Retaining best price has the potential to reduce the negative effects of discriminatory pricing for all consumers, and to maximize pharmacists' ability to provide valued, compensated drug therapy management services.

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Bristol-Myers Squibb Company

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Wayne A. Davidson
President

July 29, 1992

The Honorable Henry Waxman
Chairman, Health and the Environment
Subcommittee
Committee on Energy and Commerce
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

The Health and the Environment Subcommittee will hold a hearing July 31 on various bills dealing with prescription drug pricing. We wish to take this opportunity to state our position that it would be inappropriate to reopen the successful Medicaid drug rebate program and to move it from a market based "best price" calculation method to an arbitrary flat rebate approach. Furthermore, we vigorously oppose pending legislation to impose government price controls on vital medicines.

BACKGROUND

Bristol-Myers Squibb is a diversified pharmaceutical company whose principal businesses are pharmaceuticals, consumer products, medical devices and nutritional products. The Company is a world leader in the discovery and development of vital new medicines to save lives, save money, and improve the quality of life of our fellow citizens.

Importance of Research and Development

Research and development is the key to providing important new medicines. But it takes an enormous amount of time and money to develop pharmaceuticals—nearly \$250 million and 12 years to bring a new product to market. It is a risky venture, too, as only one of every 5,000 compounds tested ever gets FDA approval. Bristol-Myers Squibb alone will invest almost \$1 billion in pharmaceutical research this year. The U.S. drug industry will spend \$11 billion.

Our research focuses on three of the nation's leading killers—heart disease, cancer and AIDS. Over the past year, Bristol-Myers Squibb received government approval to market Videx[®], an important new drug in the fight against AIDS; Monopril[®] for hypertension; Pravachol[®] for the treatment of hypercholesterolemia; and Cefzil[®], a new broad spectrum antibiotic.

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Cost Effective Medicine

In addition to saving lives, medicines like these save money.

- Our drug Capoten®, for example, helps to dramatically reduce hospital and emergency room visits in patients with congestive heart failure.
- A year of therapy with Monopril®, our new anti-hypertensive, costs about \$325, while a serious heart attack, and follow-up treatment can cost \$50,000.

Cost effective products like these have made prescription drugs a small and declining share of health care spending. While outpatient prescription drugs consumed 12 percent of all health care spending in the early 1960's, they represent less than five percent today. Spending on prescription drugs has remained constant at one-half percent of GNP for the past 25 years.

Company Initiatives

However, national totals mean little to a citizen of modest or no resources faced with paying for a vital drug. Outlined below is what Bristol-Myers Squibb is doing to help control the costs of—and improve access to—our drugs.

The new drugs I mentioned earlier are priced at or below their leading competitors. For example, a year's therapy on Videx® is 20 percent lower in cost than a year of Retrovir® (AZT) therapy.

The Company also provides significant discounts for drugs to state and federal health programs in the form of Medicaid rebates; voluntary price reductions for the Veterans Affairs Department, Community and Migrant Health Centers and for other entities that purchase off the Federal Supply Schedule; and rebates for states' general assistance and pharmaceutical assistance programs for the elderly.

Unfortunately, many needy still fall through the cracks in our health care system. They do not have health insurance, are not eligible for Medicaid or other programs, and are financially needy. The American Heart Association (AHA) recognized this in a report last Fall about the high rate of heart disease among the uninsured. AHA asked drug companies to help needy patients obtain vital medications. Bristol-Myers Squibb responded by making its entire line of cardiovascular products available at no charge to patients that have no other source of drug coverage and are medically indigent. Since the Cardiovascular Access Program started in April it has enrolled over 14,000 doctors and provided drugs to over 1,000 patients.

This new program is a natural extension of the Company's long-standing policy of providing its prescription drugs to needy patients. For example, since 1973, the Company has had an indigent patient program for cancer patients. During the past five years alone, over 14,000 requests for assistance have been fulfilled by this program.

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The Company also provided expanded access to its AIDS drug Videx[®], prior to FDA approval, to over 23,000 patients. After FDA approval, the Company continues to offer Videx[®] free-of-charge to patients who lack drug coverage and the means to buy Videx[®].

These actions clearly demonstrate we are concerned about the cost of pharmaceuticals and the quality of patient care and committed to socially responsible drug pricing policies.

PENDING LEGISLATION

We understand the July 31 hearing will focus on legislative proposals affecting Medicaid drug price rebates, Department of Veterans Affairs drug prices, and discount drug prices to Public Health Service clinics. I would like to comment on each proposal.

Medicaid (HR 5614)

The Company opposes reopening the Medicaid prescription drug price rebate law passed in 1990 for two major reasons.

First, Congress passed the rebate law to achieve savings in Medicaid. It is a spectacular success by this criterion. The rebate law is generating tremendous savings to Medicaid, over \$6.1 billion in Fiscal Years 1991-1997 according to the CBO. In just the first five years, CBO says rebates will generate about \$800 million more in savings than previously expected.

Second, "best price" is a better way to calculate rebates than the flat percentage method contained in some proposals. "Best price" rebates directly reflect drug prices in the marketplace. The notion that "best price" will disappear, as some suggest, is misguided; competition in the market will always force companies to consider lowering their prices to increase volume and maximize revenues in the long run.

Flat rebates, by contrast, have no connection to the market place. They are more likely to shift costs to private pay patients and could ultimately deprive patients of innovative medicines.

Bristol-Myers Squibb thus encourages the subcommittee to resist efforts to needlessly revise the Medicaid rebate calculations.

Federal Supply Schedule (HR 2890)

Upon enactment of the Mikulski amendment to temporarily exempt Federal Supply Schedule (FSS) prices from the Medicaid rebate calculation, Bristol-Myers Squibb voluntarily lowered its FSS prices to match its Medicaid prices. At that time, BMS offered FSS prices on 550 line items representing 140 products. The April 8 Department of Veterans Affairs (VA) report on drug pricing said this "...will result in significant savings to the VA system." Unfortunately, Congress has allowed the Mikulski exemption to lapse.

As a result of the loss of the FSS exemption, BMS was forced to remove 75 line items affecting 16 products from the Federal Supply Schedule (FSS). I'd like to assure you that this action does not reflect any weakening of our commitment to provide voluntary discounts to federal agencies that purchase off the FSS.

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In fact, we have gone to great lengths to ensure that our FSS customers will not be adversely affected. It is important to understand that:

- o **A small portion of our products were affected.** Only 11% of our FSS-listed products and 13% of our FSS line items were removed from the FSS.
- o **There should be no impact on supply or access to our products by FSS customers.** All of the affected products are available through the depot system. In addition, we have advised all FSS customers of this action to minimize the potential for disruption. And, all of our recently launched products – Videx®, Pravachol®, Monopril®, and Cefzil® – remain on the FSS.
- o **BMS did not raise its FSS prices.** All of the affected products are available at our "best price" through the depot system.
- o **We are making special arrangements with the small number of federal customers that have been purchasing our products off the FSS but cannot purchase from the depot.**

As you can see -- federal entities that purchase off the Federal Supply Schedule continue to have access to our best prices. They simply need to purchase them from the depot, instead of the FSS system.

The Subcommittee is now considering bills to help VA get lower drug prices by rolling back FSS prices to September 1990 levels, plus inflation or renegotiating even lower prices for FSS. The penalty for not complying is exclusion from the Medicaid program.

Bristol-Myers Squibb strenuously opposes such proposals to let government control pharmaceutical prices. Price controls never have--and never will--work. The dissolution of the U.S.S.R. and the massive political and economic changes in Eastern Europe clearly make this point for us. Government price controls would severely damage one of America's most innovative and beneficial industries. The inevitable result of government price controls will be significantly less development of new and better medicines.

We encourage the Subcommittee to extend the Mikulski exemption to the end of the current FSS contract period (December 31, 1995). This would allow companies a more predictable environment to lower their prices to the VA without triggering additional rebates in the much larger Medicaid market. The temporary nature of the original Mikulski exemption created an uncertain environment which may have made it difficult for pharmaceutical companies to make long term commitments to FSS price reductions.

PHS Rebates (HR 3405)

The Subcommittee also will consider legislation to provide discounted drug prices for certain Public Health Service (PHS) clinics.

Bristol-Myers Squibb already has a discount program in place. Our experience provides valuable lessons about developing a program. Specifically, such a program needs to be targeted to broad based health clinics, such as Section 329/330, the Community and Migrant Health Centers. They can be clearly identified and certified by the federal government, have on-site pharmacy services, can account for all prescription drug products, and can avoid duplication of rebates for Medicaid prescriptions. In our program, clinic prices are set at the effective Medicaid price level, which is our best price.

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The Subcommittee should also consider the administrative complexity of this kind of legislation. The Department of Health and Human Services does not have a complete list of the entities which may be eligible for discounts beyond Section 329/330 the Community and Migrant Health Centers. (These entities are already eligible for discounts from Bristol-Myers Squibb.) Moreover, clinics are frequently part of larger health entities which serve more than the poor. Just the record keeping needed to properly target discounts would surely cost more than the program may save.

If the Committee pursues PHS drug discount legislation, we urge it to follow closely the outlines of our program described above. We would be pleased to provide you with additional details.

CONCLUSION

Bristol-Myers Squibb has demonstrated its commitment to holding down drug prices and helping to ensure access to vital medicines. We hope Congress will acknowledge and facilitate these efforts by maintaining the current status of the Medicaid drug rebate program, assisting veterans by extending the Mikulski exemption through the end of the current contract period (December 31, 1995), and crafting a drug discount program for Community and Migrant Health Centers consistent with our experience.

We look forward to working with you and other Members of the Committee on this important issue.

Sincerely,


Wayne A. Davidson

cc: Members of the Subcommittee

**Hearing Before The
House Subcommittee on Health and Environment
July 31, 1992**

The Pharmaceuticals Division of CIBA-GEIGY Corporation is pleased to submit this written testimony to the House Subcommittee on Health and Environment for its July 31, 1992 hearing on "Proposals to Reform the Medicaid Drug Rebate Program."

As a strong believer in the competitive marketplace, we share Congress' concerns regarding the ever escalating costs of providing health care in this country. We are committed to work toward solutions to control rising health care costs and to ensure that our products remain the best value for physicians, patients and third-party payors.

We also understand the growing confusion surrounding the effects of the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) and why some in Congress believe the pharmaceutical industry is taking advantage of this situation. Some of the concerns we have heard can be summed up by the following questions:

- Are the Departments of Veterans Affairs and Defense paying more for prescription drugs now than before the passage of OBRA '90?
- Are the "best prices" to Medicaid evaporating? Is this affecting Medicaid's projected savings?
- Can Congress ensure that the Departments of Defense and Veterans Affairs, as well as private sector providers, receive discounts on their prescription drug purchases?

These questions are valid concerns and we intend to address them in our testimony. We believe that this Subcommittee will discover that the fundamental cause of these concerns can be traced back to the use of the "best price" calculation for determining Medicaid rebates. As will be discussed later in this testimony, legislative enactment of "best price" threatens the ability of companies, like CIBA-GEIGY, to provide discounts or rebates to federal, state and private sector entities.

The rebate formula enacted in OBRA '90, commonly called "best price," has hindered us from competing in the marketplace by favoring companies who provide little or no discounts to government or private sector customers. We believe a solution can be found to address this problem. CIBA-GEIGY stands ready to work closely with this Subcommittee to address this problem, resolve Congressional concerns and restore competitiveness to the marketplace.

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In our testimony, CIBA-GEIGY will address the following three points:

1. The competitive marketplace cannot function effectively when traditional discounts to public and private customers are threatened;
2. The adoption of a fixed rebate for Medicaid would redress this problem and allow price competition to flourish; and
3. The expansion of a flat discount or rebate to the Department of Veterans Affairs, the Department of Defense and Public Health Service clinics would provide government with predictable and substantial savings from pharmaceutical manufacturers.

The Competitive Marketplace

OBRA '90 requires all pharmaceutical manufacturers to provide Medicaid with a rebate on its prescription drug sales equal to the difference between its deepest discount in the marketplace (either private or public contract) and the average manufacturer price for that prescription drug.

CIBA-GEIGY supports the fundamental premise of OBRA '90 - manufacturers should provide their best customers with savings on their prescription drug products. To that end, we offer substantial discounts to customers such as Health Maintenance Organizations, hospitals and nursing home providers as well as governmental entities such as the Department of Veterans Affairs, the Department of Defense and Public Health Service clinics.

As predicted by the Congressional Budget Office, however, the use of "best price" to calculate Medicaid rebates has disrupted the marketplace and has had the end result of lowering discounts to organizations and providers, including the federal government. In fact, based on the testimony submitted to this Subcommittee on July 31, 1992, representing Health Maintenance Organizations, hospitals and the Department of Veterans Affairs, "best price" was identified as the root cause of declining discounts. Virtually all the organizations testifying at the hearing indicated discounts have either been reduced or lost as a result of the "best price" provision.

Clearly, Congress recognized that the marketplace would be forced to adapt to the "best price" concept, and the possibility of diminishing discounts, when they drafted the legislation. This is precisely why Congress inserted a three-year Phase-in program effectively capping the "rebate exposure" of pharmaceutical manufacturers. What Congress failed to recognize, however, was that the imposition of "best price" would serve to undercut the ability companies, like CIBA-GEIGY, to offer discounts.

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Traditionally, the pharmaceutical industry has given discounts for a wide array of reasons. In CIBA-GEIGY's case, we provide discounts to those customers who fall under either of the following categories:

1. Larger purchasers with in-house pharmacies who purchase directly from pharmaceutical firms, i.e., take full possession of our products. This reduces our administrative costs, as opposed to the administrative complications intrinsic to Medicaid rebate agreements.
2. Third-party payors who have the ability to shift market share or meet annual volume requirements, as agreed to with the manufacturer.

Since Medicaid does not fall under either of these categories, similar discounts do not apply.

CIBA-GEIGY, with a long tradition of providing discounts, has been compelled to reexamine the level and extent of our discounts. Although we continue to offer discounts, the effect of requiring us to offer the same discounts to Medicaid that we provide to other larger purchasers has had a chilling effect on the level of discounts we can afford to offer our other customers.

Our company, along with many other manufacturers, opposed the "best price" concept because it would compel us to offer Medicaid the same deep discounts already negotiated with other large customers. These prices were negotiated prior to the existence of OBRA '90 when the financial ramifications of a discount did not extend beyond an individual customer.

CIBA-GEIGY understands the need for federal programs to contain rising costs and is willing to guarantee a fixed percentage rebate that would yield the same savings but not undermine the competitive nature of the marketplace.

Fixed Rebates vs. "Best Price"

H.R. 5614, introduced by Representative Slattery, would address many of the concerns Congress has voiced over the changing nature of pharmaceutical discounts in the public and private sectors. Representative Slattery's bill would change the calculation of Medicaid rebates from "best price" to a fixed percentage and would achieve the following goals:

- Generate the same savings anticipated by government from rebates based upon "best price" calculations. According to CBO's latest calculations, a fixed discount would yield the same savings.
- Restore competition to the marketplace, allowing companies to compete on price and value.

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- Yield predictable and guaranteed savings which cannot be assured with a "best price" rebate. The unpredictability of "best price" discounts cannot allow government to adequately budget for future fiscal years. A fixed percentage discount is predictable and guaranteed.
- Result in less costly administration costs since the Health Care Financing Administration and the states would not have to adjust their calculations each month based upon the latest "best price."

Enactment of H.R. 5614 also would address the concerns of two other bills discussed at this hearing: Representative Wyden's H.R. 3405 which would ensure that Public Health Service clinics receive Medicaid-like discounts from manufacturers and Representative Montgomery's H.R. 2690, which would roll back prices to the Department of Veterans Affairs to October, 1990 levels.

Clearly, both bills seek to address the serious effects of OBRA '90 on prescription drug discounts to government entities. CIBA-GEIGY supports Representative Wyden's proposal and, although we oppose any mandated rollback of prices, we believe the VA should receive at least the same level of discounts as other federal customers, including Medicaid.

CIBA-GEIGY's Position

CIBA-GEIGY has had and continues to have a firm policy of providing discounts to private and public sector customers. Despite the effects of OBRA '90, we continue to provide the Departments of Veterans Administration and Defense with discounts ranging from 10 - 75 percent of our Average Manufacturers' Price. We also anticipate rebating state Medicaid programs nearly \$50 million in 1992.

These savings to government, however, are a function of the current "best price" calculation. As "best price" diminishes in the marketplace, according to the CBO, predictability of future savings cannot be guaranteed. Predictability for business also is important since we need to anticipate future expenses in our own budgets. Therefore, CIBA-GEIGY suggests that Congress amend OBRA '90 with H.R. 5614, replacing the existing "best price" calculation with a fixed discount. Additionally, this fixed discount should apply to all federal and state customers, thereby ensuring that all government payors receive equivalent discounts.

The benefits to government, business and private sector customers would be substantial. Government would continue to receive equivalent savings, business would achieve predictability and HMOs, hospitals and nursing home providers would become the recipients of a more competitive marketplace.

Conclusion

Thus, for our company, the issue is not whether government and other large purchasers deserve discounts. We have a long-standing commitment to provide

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our best customers with substantial discounts on our prescription drug products. The issue is whether pharmaceutical manufacturers can offer these discounts in a predictable manner, guaranteeing savings to all of our valued customers.

Adopting Representative Slattery's bill would ensure that substantial discounts are provided while also ensuring that savings are guaranteed.

As a manufacturer of innovative and cost-effective prescription medicines, CIBA-GEIGY firmly believes in the dynamics of a competitive marketplace. Competition allows purchasers of our products to make informed decisions regarding the value, quality and price of our medicines vs. other therapies. Equally as important, competition reduces costs to a health care system already beset by financial pressures.

CIBA-GEIGY wishes to work closely with this Subcommittee to assure this solution is adopted.

Generic Pharmaceutical Industry Association

IMPACT OF OBRA '90 ON GENERIC PHARMACEUTICAL FIRMS

EXECUTIVE SUMMARY

- The ten firms studied accounted for \$1.08 billion in sales during 1991, a substantial share of the U.S. market for non-originator drug products.
- Generic firms lost 30.91% of their net income due to Medicaid rebates while brand firms lost about 6.83% of their net income from the basic rebate.
- The impact of the Medicaid basic rebate on profitability (net income) of generic firms was more than four times greater than the impact on brand firms.
- Brand firms have two to three times as much room as generic firms in their budgets to absorb Medicaid rebates with gross profit margins of 64% to 80% for brand firms versus 30% for generic firms.

IMPACT OF OBRA '90 ON GENERIC PHARMACEUTICAL FIRMS

FINAL REPORT

Medicaid programs purchase about 12 percent of all outpatient prescriptions in the U.S. market. This makes Medicaid the largest single purchaser of outpatient prescriptions, yet Medicaid found that it was often paying the highest price at the manufacturer level for these prescription drug products. Consequently, the Omnibus Budget Reconciliation Act of 1990 (OBRA '90) included legislation to provide the Medicaid program with rebates on pharmaceutical product purchases. Pharmaceutical manufacturers are required to pay the Medicaid program a rebate for all units of drug product used by Medicaid recipients. Participation in the rebate program is a condition required of all manufacturers wishing to have their drug products covered by the Medicaid program.

The basic rebate for single source and innovator multiple source (branded) products was set at a minimum of 12.5% for the first two years (1991 and 1992) and 15%, thereafter. The basic rebate for non-innovator multiple source (generic) drug products was set at 10% for the first three years (1991-93) and 11% in the years after 1993. On the surface generic firms appear to be contributing a lower amount than the brand name firms. However, one must remember that generic firms typically sell the same drug product at one-fourth to one-half the price of the brand name drug product. Consequently, generic firms have gross margins of 30% while brand name firms have gross margins ranging from 64% to 80%. Net margins also differ substantially with brand firms having 15% net income as a percent of sales and generic firms having 2% to 3% net income. This means that brand firms have more than twice as much room as generic firms in their budgets to absorb Medicaid rebates. Because of these differences in the cost structure and in the profitability of brand versus generic firms, the generic firms are being penalized much more than the brand firms by the Medicaid rebate legislation.

OBJECTIVES

This study was conducted to determine the impact of OBRA '90 on generic pharmaceutical firms. Several research questions were addressed by this study.

- (1) Did generic firms experience a change in profitability after implementation of the Medicaid rebate program contained in OBRA '90?
- (2) Was there a differential effect from the Medicaid rebate program on large ($\geq \$100,000,000$ sales per year) versus small ($< \$100,000,000$ sales per year) generic pharmaceutical firms?
- (3) Was there a differential effect from the Medicaid rebate program on generic versus brand pharmaceutical firms?

STUDY METHODS

A mailed survey instrument was prepared to request information from generic firms on: sales, cost of production, Medicaid rebates, administrative costs of rebate program, and volume of Medicaid business. A copy of the survey form is attached as Appendix A. Surveys were mailed to 16 generic pharmaceutical firms who were members of the Generic Pharmaceutical Industry Association or the National Association of Pharmaceutical Manufacturers. Ten of the 16 firms responded with complete information for a 62.5% response rate. The participating firms were promised anonymity so the data reported in this study are shown only at aggregate levels. The participating firms varied in size and accounted for \$1.08 billion in generic pharmaceutical sales during 1991 in the United States. This represents a substantial share of the U.S. market for non-originator drug products.

RESULTS

The results are divided into several sections covering: description of the responding firms, changes in profitability over time, differences between large and small generic firms, and differences between generic and brand name firms. First, a description of the firms responding is provided in Table 1. The average 1991 total sales revenue of these ten generic firms was \$108 million. Four of the firms had 1991 total sales revenue in excess of \$100 million while 6 firms had less than that amount. Medicaid sales accounted for 14.5% of total sales for the average generic firm and these firms paid an average of \$1.5 million in rebates to Medicaid in 1991.

Over the past three years (1989-1991) generic firms have continued to experience growth in sales revenue as shown in Table 2. Annual sales revenue in the average generic firm grew from \$87.6 million in 1989, to \$102.2 million in 1990, and to \$108.2 million in 1991. Net income, however, decreased substantially in 1991 compared with the two previous years. The average generic firm's net income in 1989 was \$3.6 million and in 1990 it was \$3.8 million. The average generic firm's net income in 1991 decreased to \$2.2 million, although if the OBRA '90 rebate program had not been in place the net income would have been \$3.2 million. Net income as a percent of sales revenue for generic firms was 4.07% in 1989 and 3.74% in 1990. The net income of the average generic firm in 1991 was 2.05%, but would have been 2.97% without the Medicaid rebate program.

The role of the Medicaid rebate program was examined by determining the Medicaid rebates each firm paid and the administrative costs to the firm of participating in the program. The average generic firm paid \$1,568,555 in Medicaid rebates in 1991 (Table 1). Their administrative costs from participation in Medicaid averaged \$107,445 for 1991. These rebate-related expenses less the additional tax liability were added back into each firm's net income to determine what the net income

would have been without the Medicaid rebate program. Instead of a 2.05% net income in 1991, the average firm would have experienced a 2.97% net income. Without the Medicaid rebate program the average generic firms net income would have been an additional 0.92% of sales revenue. The difference in net income dollars due to Medicaid rebates was a drop from \$3,216,060 to \$2,221,941. This decline of \$994,119 amounts to 30.9% reduction in net income.

Four of the firms studied experienced a net loss in 1991 and a fifth firm was at the break even point with no net income. Only five of the ten generic firms had a profit in 1991. One of the ten firms went from a profit to a loss because of the Medicaid rebate program and another firm went from a profit to break even. Three other firms had even greater losses due to the Medicaid rebate program.

The second research question concerned the impact of OBRA '90 rebates on the profitability of large and small generic firms. Basic descriptive information is provided on large and small generic firms in Table 1. Large firms were defined as those with greater than \$100,000,000 in total sales revenue in 1991 and small firms were those with less than \$100,000,000 in total sales revenue in 1991. Profitability of both large and small generic firms was affected by Medicaid rebates. Large firms saw their net income drop from 2.83% to 1.92% of sales revenue, while small firms saw their net income drop from 3.36% to 2.45%. The decline for large firms, 0.91%, was virtually identical to the decline for small firms, 0.92%. Medicaid rebates accounted for a 32.1% decrease in net income of the large firms and a 27.3% decrease for the small firms. The profitability of both large and small generic firms appears to have been influenced substantially and similarly by the Medicaid rebate program.

In order to compare the impact of OBRA '90 rebates on brand and generic firms, two hypothetical firms each with \$100,000,000 in total sales revenue were created. The percentage distribution of sales revenue for the generic firm was based on the average generic firm in this study. The percentage distribution of sales revenue for the brand firm was based on information presented in Report to Congress on Manufacturers' Prices and Pharmacists' Charges for Outpatient Drugs Covered By Medicare (Washington, DC: U.S. Department of Health and Human Services, May 1989). An important factor to note is that the gross profit margin for generic and brand name firms are quite different. Gross profit margin is total sales revenue minus production costs. Generic firms in this study had a gross profit margin of about 30% while brand firms have gross profits between 64% and 80% (The Pink Sheet, June 15, 1992). This means that brand firms have more than twice as much room as generic firms in their budgets to absorb Medicaid rebates. As shown in Table 3, the Medicaid rebate program meant that the average generic firm's net income decreased from 2.97% to 2.05% of sales revenue, while the typical brand firm's net income decreased from 15.00% to 13.98% of sales revenue. Most of this decrease in the brand firm's net income will likely be minimized by price increases to retailers for single source products, but strong competitive pressures will not allow generic firms to raise prices

to offset the impact of the basic Medicaid rebate. When the decline in net income dollars due to Medicaid rebates is examined, generic firms lost 30.91% of their net income while brand firms lost 6.83% of their net income due to the basic rebate (Figure 1). In other words, the impact on net income of generic firms was more than four times greater than the impact on brand firms.

The impact of the Medicaid rebate program is even more dramatic when profitability of Medicaid sales is determined. Table 4 presents the impact of rebates on a generic and brand firm which each have \$10,000,000 in sales to Medicaid. When considering the profitability of only those drug products sold to Medicaid rather than all sales revenue, the impact of Medicaid rebates is substantial. The typical brand firm would experience net income as a percent of Medicaid sales of about 15.0% without the rebate program and 2.98% with the rebate program. The average generic firm would have net income as a percent of Medicaid sales of 2.97% without Medicaid rebates and -3.02% with the Medicaid rebate program. This means that generic firms shifted from a modest profit to a modest loss because of the Medicaid rebate program. Brand firms shifted from a substantial profit to a modest profit as a result of the Medicaid rebate program.

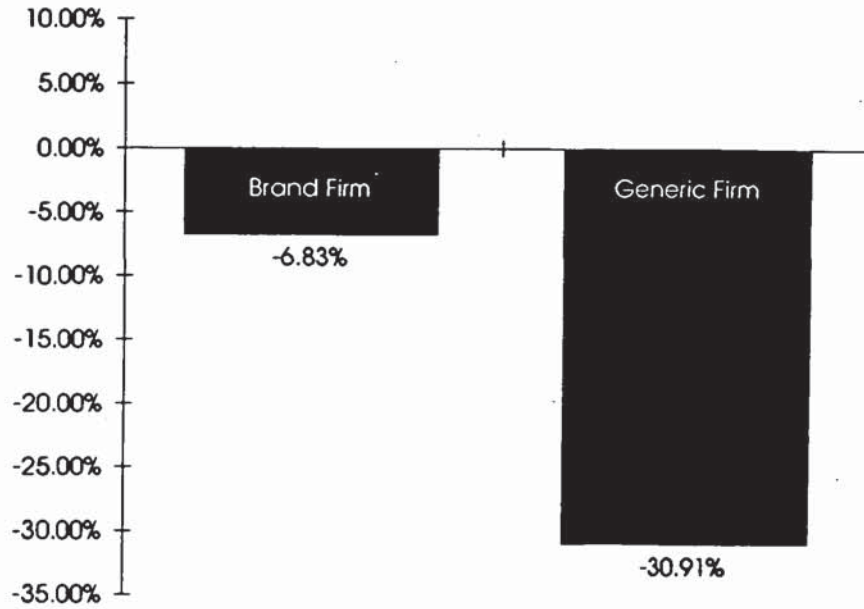
CONCLUSIONS

Several conclusions can be drawn from the experience of 10 generic firms which accounted for a sizeable share of non-originator generic pharmaceutical sales in the United States in 1991. Generic firms experienced a substantial decline in profitability after the implementation of the Medicaid rebate program. Results of this study indicate that generic firms experienced a 30.9% decline in profits in 1991 due to the Medicaid rebate program. One firm, which would have had a profit in 1991, shifted to a loss because of the rebates, while another firm went from a profit to break even and three other firms had even greater losses. Large generic firms noticed a greater decline in profitability than did small generic firms, 32.1% versus 27.3%, although both had substantial losses.

Finally, generic firms' profitability declined substantially more from the Medicaid rebate program than would be expected for a typical brand firm. The typical brand firm saw net income decrease by 6.83% versus a 30.91% decrease for the average generic firm. When net income from Medicaid sales were considered generic firms were found to have a 3.02% loss with rebates versus a 2.97% profit without the rebates. Brand firms saw net income from Medicaid drop from a 15.0% profit to a 2.98% profit with implementation of the rebate program. Therefore, the basic rebate of the Medicaid rebate program had a substantially greater impact on the profits of generic firms than it did upon the profits of brand firms. The impact of OBRA '90 Medicaid rebates on profitability was more than four times greater for generic firms than for brand firms.

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Figure 1
Net Income of Generic Firms Declines More Than
Four Times as Much as Brand Firms Due To
Basic Medicaid Rebate



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TABLE 1
IMPACT OF OBRA '90 ON GENERIC FIRMS IN 1991

<u>1991 Calendar Year Data</u>	<u>Average Large Generic Firm (4)</u>	<u>Average Small Generic Firm (6)</u>	<u>Average Generic Firm (10)</u>
Total Sales Revenue	\$203,815,250	\$44,516,777	\$108,236,166
Production Costs	\$141,396,750	\$30,690,896	\$74,973,238
Other Costs (Adm./Mkt/etc)	\$55,226,087	\$12,124,255	\$29,364,988
Medicaid Rebate Payments	\$3,065,750	\$570,424	\$1,568,555
Medicaid Rebate Admin. Expense	\$204,663	\$42,633	\$107,445
Total Cost of Sales	\$199,893,250	\$43,428,209	\$106,014,225
Net Income (\$) (w/OBRA)	\$3,922,000	\$1,088,568	\$2,221,941
Net Income (%) (w/OBRA)	1.92%	2.45%	2.05%
Net Income (\$) (w/o OBRA)	\$5,777,694	\$1,496,652	\$3,216,060
Net Income (%) (w/o OBRA)	2.83%	3.36%	2.97%
Change in Net Income (\$)	\$1,855,694	\$408,084	\$994,119
Change in Net Income (%)	0.91%	0.92%	0.92%
% Decline in Net Income Due to OBRA	32.12%	27.27%	30.91%
% of Total Sales to Medicaid	15.04%	12.81%	14.49%

TABLE 2
GENERIC FIRMS' SALES AND NET INCOME: 1989 TO 1991

<u>Item and Year</u>	<u>Average Large Generic Firm (4)</u>	<u>Average Small Generic Firm (6)</u>	<u>Average Generic Firm (10)</u>
<u>Total Sales Revenue</u>			
1989	\$155,383,750	\$42,339,437	\$87,557,162
1990	\$189,013,250	\$44,306,472	\$102,189,183
1991 w/o OBRA	\$203,815,250	\$44,516,777	\$108,236,166
1991 w/ OBRA	\$203,815,250	\$44,516,777	\$108,236,166
<u>Net Income (\$)</u>			
1989	\$4,734,500	\$2,784,905	\$3,564,743
1990	\$5,768,250	\$2,525,326	\$3,822,496
1991 w/o OBRA	\$5,777,694	\$1,496,652	\$3,216,060
1991 w/ OBRA	\$3,922,000	\$1,088,568	\$2,221,941
<u>Net Income (%)</u>			
1989	3.05%	6.58%	4.07%
1990	3.05%	5.70%	3.74%
1991 w/o OBRA	2.83%	3.36%	2.97%
1991 w/ OBRA	1.92%	2.45%	2.05%

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TABLE 3
IMPACT OF OBRA '90 ON TOTAL NET INCOME OF GENERIC AND BRAND FIRMS*

<u>1991 Calendar Year Data</u>	<u>Average Generic Firm</u>		<u>Hypothetical Brand Firm</u>	
	<u>1991 \$</u>	<u>% of Sales</u>	<u>1991 \$</u>	<u>% of Sales</u>
Total Sales Revenue	\$100,000,000	100.00%	\$100,000,000	100.00%
Production Costs	\$69,268,194	69.27%	\$36,000,000	36.00%
Other Costs (Adm./Mkt/etc)	\$27,130,477	27.13%	\$48,424,000	48.42%
Medicaid Rebate Payments	\$1,449,196	1.45%	\$1,500,000	1.50%
Rebate Admin. Expenses	\$99,269	0.10%	\$100,000	0.10%
Total Cost of Sales	\$97,947,136	97.95%	\$86,024,000	86.02%
Net Income (\$) (w/OBRA)	\$2,052,864	2.05%	\$13,976,000	13.98%
Net Income (\$) (w/o OBRA)	\$2,971,336	2.97%	\$15,000,000	15.00%
Change in Net Income (\$)	\$918,472	0.92%	\$1,024,000	1.02%
% Decline in Net Income Due to OBRA	30.91%		6.83%	
% of Total Sales to Medicaid Basic Medicaid Rebate as % Total Sales Revenue	14.49%		12.00%	
	10.00%		12.50%	

* For comparison the impact of OBRA '90 on a generic firm and a hypothetical brand firm each with \$100,000,000 in total sales revenue are shown.

TABLE 4
IMPACT OF OBRA '90 ON MEDICAID NET INCOME OF GENERIC AND BRAND FIRMS*

<u>1991 Calendar Year Data</u>	<u>Average Generic Firm</u>		<u>Hypothetical Brand Firm</u>	
	<u>1991 \$</u>	<u>% of Sales</u>	<u>1991 \$</u>	<u>% of Sales</u>
Medicaid Sales Revenue	\$10,000,000	100.00%	\$10,000,000	100.00%
Production Costs	\$6,926,819	69.27%	\$3,600,000	36.00%
Other Costs (Adm./Mkt/etc)	\$2,365,108	23.65%	\$4,842,400	48.42%
Medicaid Rebate Payments	\$1,000,000	10.00%	\$1,250,000	12.50%
Rebate Admin. Expenses	\$9,927	0.10%	\$10,000	0.10%
Total Cost of Sales	\$10,301,854	103.02%	\$9,702,400	97.02%
Net Income (\$) (w/OBRA)	(\$301,854)	-3.02%	\$297,600	2.98%
Net Income (\$) (w/o OBRA)	\$297,134	2.97%	\$1,500,000	15.00%
Change in Net Income (\$)	(\$598,988)	-5.99%	(\$1,202,400)	-12.02%
% Decline in Net Income Due to OBRA	201.59%		80.16%	
Basic Medicaid Rebate as % Total Sales Revenue	10.00%		12.50%	

* For comparison the impact of OBRA '90 on a generic firm and a hypothetical brand firm each with \$10,000,000 in Medicaid sales revenue are shown.

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APPENDIX A

The Survey Instrument

IMPACT OF MEDICAID REBATES ON GENERIC FIRMS

Company _____ Phone # _____

Name of Contact _____ FAX # _____

I. ANNUAL SALES AND COST OF SALES

Please complete all items below for the calendar year, if possible.

Information is for: _____ calendar year; _____ fiscal year; fiscal year term _____ to _____

	1989	1990	1991
A. Total Sales \$	_____	_____	_____
B. Cost of Sales \$ (B = sum of C to J)	_____	_____	_____
<i>Breakdown of Cost of Sales</i>			
C. Production Costs	_____	_____	_____
D. Admin. Central	_____	_____	_____
E. Sales & Marketing	_____	_____	_____
F. Distribution	_____	_____	_____
G. Medicaid Rebates	0	0	_____
H. Taxes	_____	_____	_____
I. Other	_____	_____	_____
J. Other	_____	_____	_____
K. Net Income (K = A - B)	_____	_____	_____

	1989	1990	1991
What % of your Sales (\$) were to patients covered by Medicaid program in each year? (Use your best estimate)	_____	_____	_____

	1989	1990	1991
Specify, basis for your estimate: (e.g., Sales data, IMS, Medicaid, other)	_____	_____	_____

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II. ADMINISTRATIVE COSTS OF MEDICAID REBATE PROGRAM

	All Capital Expenditures	1991 Annualized Expenses
Direct Salaries and Benefits	_____	_____
Management Support	_____	_____
Rent (Allocated Occupancy Costs)	_____	_____
Supplies and Materials	_____	_____
Computer Software (Purchased or Developed)	_____	_____
Consulting Services	_____	_____
Syndicated Market Share Data (IMS, PDS, other)	_____	_____
Other, specify:	_____	_____
Other Specify:	_____	_____
TOTAL	_____	_____

Approximately what % of your sales (\$) in 1991 were for:

Products you manufactured and you distributed	_____ %
Products you manufactured and someone else distributed	_____ %
Products someone else manufactured and you distributed	_____ %

How much of the Medicaid rebate did your company pay in 1991?

(Check the category which applies, and if part was paid indicate % of Medicaid rebate you paid.)

	All	Part (%)	None
Products you manufactured and you distributed	_____	(_____ %)	_____
Products you manufactured and someone else distributed	_____	(_____ %)	_____
Products someone else manufactured and you distributed	_____	(_____ %)	_____

Please return survey to:

Stephen W. Schondelmeyer
Professor and Director, PRIME Institute
Health Sciences Unit F 7-159
University of Minnesota
Minneapolis, Minnesota 55455
Phone: (612) 624-9931; FAX: (612) 625-9931

**Written Statement of
William J. Wooldridge
President Of The
Health Industry Group Purchasing Association**

Introduction

Mr. Chairman and members of the subcommittee, my name is William J. Wooldridge, Founder/Chairman of the Board for MedEcon Services, Inc. and President of the Health Industry Group Purchasing Association. On behalf our nineteen organizational members, I appreciate the opportunity to submit the Association's views on legislation regarding the purchase of prescription drugs by public and private payors and programs and the experiences we have had since the Medicaid prescription drug rebate program established under the Omnibus Budget Reconciliation Act of 1990 (OBRA 90, P.L. 101-508) was enacted.

The Health Industry Group Purchasing Association (HIGPA) is a broad-based trade association whose members are organizations engaged in providing cost containment services, such as group purchasing, to health care providers. Our membership is made up of for-profit and not-for-profit corporations, voluntary purchasing groups, state, regional and metropolitan trade associations, multi-hospital systems and health care provider alliances.

HIGPA's nineteen members represent over 3,600 health care providers and individually maintain a portfolio of hundreds of purchasing agreements covering hundreds of thousands of individual items. Today, HIGPA members service nearly 58% of all the acute care hospitals in the country.

Many hospitals and other providers have long purchased prescription drugs in large quantities for use by their patients. For most hospitals and health care providers, the prices of these products is negotiated by a group purchasing organization (GPO) to which the provider belongs or is affiliated. GPOs negotiate prices of goods and services for participating health care providers at costs below those which the members would be able to obtain individually. GPOs are able to obtain significant discounts because of the large volume of purchases represented by its members and other economies arising from marketing and distribution that the manufacturer re-

alizes from this type of sale.

Prior to the enactment of OBRA 90, nearly all pharmaceutical manufacturers offered reduced prices to large purchasers in order to improve efficiency of supplying their customers and to increase their share of the market in comparison to their competitors. The discounts negotiated by large purchasers like HIGPA members have enabled us to control our drug costs, which, in turn, has had a beneficial effect on overall health care costs.

HIGPA members have successfully worked to reduce health care costs through negotiated contracts with manufacturers and distributors providing the goods and services used by its member health care providers in meeting the needs of their patients. Congress has previously acknowledged the positive impact that GPOs have had on the health care industry.

HIGPA fully supports a program which provides rebates for pharmaceuticals procured for the Medicaid program as was the objective of OBRA 90. However, the "best price" provision of the law has failed to make pharmaceutical manufacturers full partners in Medicaid cost containment — to the contrary — considerable cost shifting has caused price increases to private payors and institutional providers. Moreover, we have learned that many of our members' contracts have not been extended beyond the end of the year, a phenomenon which we attribute to the law's recent implementation.

Background / Current Law

Section 4401 (Reimbursement for Prescribed Drugs) of the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) requires pharmaceutical manufacturers as of January 1, 1991, to sell prescription drugs to state Medicaid programs at the same "best price" policy traditionally available to large volume purchasers like the Veterans Affairs Department and the Department of Defense.